

LYME DISEASE AND “CHRONIC LYME”

What is the controversy all about?

August 5, 2008

Samuel Shor, MD, FACP
Associate Clinical Professor
George Washington University
Health Care Sciences
Internal Medicine of Northern Virginia
1860 Town Center Drive #230
Reston, Virginia 20190
703 709-1119



Lyme Disease



Chronic Lyme Disease Overview

- ▣ The Major Players and the Present Guidelines
- ▣ Chronic Fatigue
 - Chronic Fatigue Syndrome or CFS
 - Chronic Lyme Disease
 - ▣ The literature
 - ▣ Case studies and proposed research
- ▣ Guidelines revisited and Where do we go from here?

The Major Players



Infectious
Diseases Society of
America

vs.



International Lyme and
Associated Diseases
Society

Chronic Lyme- IDSA vs. ILADS

The controversy		
		
Post Lyme fatigue [ie after "appropriate treatment"]	is noninfectious, i.e. due to "something else"*	often related to ongoing infection AND other phenomena*
Chronic Lyme infection	doesn't exist	very much exists and often contributes to "post lyme" and other causes of chronic fatigue and other conditions.
*often associated with other phenomena: Fibromyalgia, sleep disorders, dysautonomias [blood pressure control issues], endocrine disorders, etc		

IDSA

Infectious Diseases Society of America

2006

IDSA GUIDELINES

The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America

Gary P. Worme,¹ Raymond J. Dattwyler,² Eugene D. Shapiro,^{3,4} John J. Halperin,^{5,6} Allen C. Steere,⁷ Mark S. Klemperer,⁸ Peter J. Krause,⁹ Johan S. Bakken,¹⁰ Franc Strle,¹¹ Gerold Sasek,¹² Linda Bockenstedt,¹³ Darland Fisk,¹⁴ J. Stephen Douglas,¹⁵ and Robert B. Nadelman¹⁶

¹Division of Infectious Diseases and ²Allergy, Immunology, and Rheumatology, Department of Medicine, New York Medical College, White Plains, New York; ³New York University School of Medicine, New York, New York; ⁴Atlantic Neuroscience Institute, Summit, New Jersey; ⁵Departments of ⁶Neurology and ⁷Psychiatry and ⁸Public Health and ⁹Section of Rheumatology, Department of Medicine, Yale University School of Medicine, New Haven, and ¹⁰Department of Pediatrics, University of Connecticut School of Medicine and ¹¹Connecticut Children's Medical Center, Hartford; ¹²Division of Rheumatology, Allergy, and Immunology, Massachusetts General Hospital, Harvard Medical School, and ¹³Thomas University School of Medicine and ¹⁴Boston Medical Center, Boston, Massachusetts; ¹⁵Section of Infectious Diseases, St. Luke's Hospital, Olatu, Minnesota; ¹⁶Division of Medical Microbiology, Department of Pathology, The Johns Hopkins Medical Institutions, Baltimore, Maryland; ¹⁷Department of Infectious Diseases, University Medical Center, Lundgren, Sweden; and ¹⁸Medical University of Vienna, Vienna, Austria

Evidence-based guidelines for the management of patients with Lyme disease, human granulocytic anaplasmosis (formerly known as human granulocytic ehrlichiosis), and babesiosis were prepared by an expert panel of the Infectious Diseases Society of America. These updated guidelines replace the previous treatment guidelines published in 2000 (Clin Infect Dis 2000; 31[Suppl 1]:i1-i14). The guidelines are intended for use by health care providers who care for patients who either have these infections or may be at risk for them. For each of these *Ixodes* tickborne infections, information is provided about prevention, epidemiology, clinical manifestations, diagnosis, and treatment. Tables list the doses and durations of antimicrobial therapy recommended for treatment and prevention of Lyme disease and provide a partial list of therapies to be avoided. A definition of post-Lyme disease syndrome is proposed.

EXECUTIVE SUMMARY

Background

Lyme disease is the most common tickborne infection in both North America and Europe. In the United

States, Lyme disease is caused by *Borrelia burgdorferi*, which is transmitted by the bite of the tick species *Ixodes scapularis* and *Ixodes punctatus*. Clinical manifestations most often involve the skin, joints, nervous system, and heart. Extracutaneous manifestations are less commonly seen than in earlier years. Early cutaneous infection with *B. burgdorferi* is called erythema migrans, which is the most common clinical manifestation of Lyme disease. *I. scapularis* may also be infected with and transmit *Anaplasma phagocytophilum* (previously referred to as *Ehrlichia phagocytophilum*) and/or *Babesia microti*, the primary cause of babesiosis. Thus, a bite from an *I. scapularis* tick may lead to the development of Lyme disease, human granulocytic anaplasmosis (HGA), formerly known as human granulocytic ehrlichiosis, or babesiosis as a single infection or, less frequently, as a coinfection. Clinical findings are sufficient

Received 21 August 2006; revised 17 August 2006; electronically published 2 October 2006.
These guidelines were developed and issued in behalf of the Infectious Diseases Society of America.
It is important to write that guidelines issued always assume the standard of care among patients. They are not intended to impact physician judgment with respect to patients who have unusual clinical situations. The Infectious Diseases Society of America considers it a core principle to be in relation with the patient's dissemination, regarding their responsibility to meet the physician in the light of each patient's individual circumstances.
Reprints or correspondence: Dr Gary P. Worme, Box 240, White Plains, New York 10622 (worme@downstate.edu).
Clinical Infectious Diseases 2006; 43:1089-1094.
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0950-2688/06/431089-06\$15.00

Chronic Lyme Disease

▣ IDSA:

- “there is no convincing biologic evidence for the existence of symptomatic chronic *B burgdorferi* infection among patients after receipt of recommended treatment regimens for Lyme disease. Antibiotic therapy has not proven to be useful and is not recommended for patients with chronic (>6 months) subjective symptoms after recommended treatment regimens”
- Virtually all of their recommended treatment options are for no more than 28days.

Wormser PG et al The Clinical Assessment, Treatment and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babebiosis: Clinical Practice Guidelines by the Infectious Disease Society of America *CID* 2006;43 (1 November) 1089-1134

Chronic Lyme Disease IDSA continued

- ▣ “a more prolonged initial treatment course of antibiotics does not improve the rate of resolution of symptoms”
- ▣ “In many patients, post treatment symptoms appear to be more related to the aches and pains of daily living rather than to either Lyme disease or a tick-borne coinfection.”

Chronic Lyme Disease IDSA continued

- ▣ Unfortunately, it is apparent that the term 'chronic Lyme disease' is also being applied to patients with vague, undiagnosed complaints who have never had Lyme disease. *When adult and pediatric patients regarded as having chronic Lyme disease have been carefully reevaluated at university-based medical centers, consistently, the majority of patients have had no convincing evidence of ever having had Lyme disease, on the basis of the absence of objective clinical, microbiologic, or serologic evidence of past or present B. burgdorferi infection"*

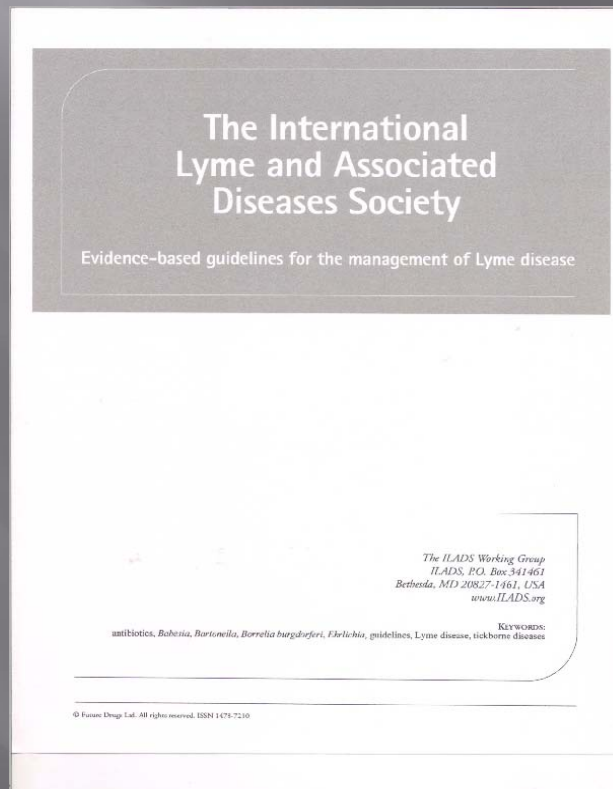
Chronic Lyme-Diagnosis

- ▣ IDSA
 - “2 tiered system” as recommended by the CDC

- ▣ ILADS
 - This two tiered system is flawed and too insensitive for which alternative options need to be considered

ILADS

International Lyme and Associated Diseases Society 2004



Chronic Lyme Disease-ILADS

▣ ILADS

- “For the purposes of the ILADS guidelines, ‘chronic Lyme disease’ is inclusive of persistent symptomatology including fatigue, cognitive dysfunction, headaches, sleep disturbance and other neurologic features....the patient may relapse in the absence of another tick bite or erythema migrans rash, or be poorly responsive to antibiotic treatment (refractory Lyme disease).”

The ILADS Working Group. Evidence-based guidelines for the management of Lyme disease. *Expert Rev Anti-Infect. Ther* 2004; 2(suppl): S1-S13

Lyme Disease- Development of the controversy

- ▣ Best described given my personal evolution:
 - Management of Chronic Fatigue
 - ▣ Personal area of interest since the late 1980s
 - Perspective of ILADS
 - ▣ Evolving awareness as the pariah
 - ▣ To visionaries
 - Practical implications
 - ▣ Management of chronic fatigue and other conditions
 - Theoretical and research

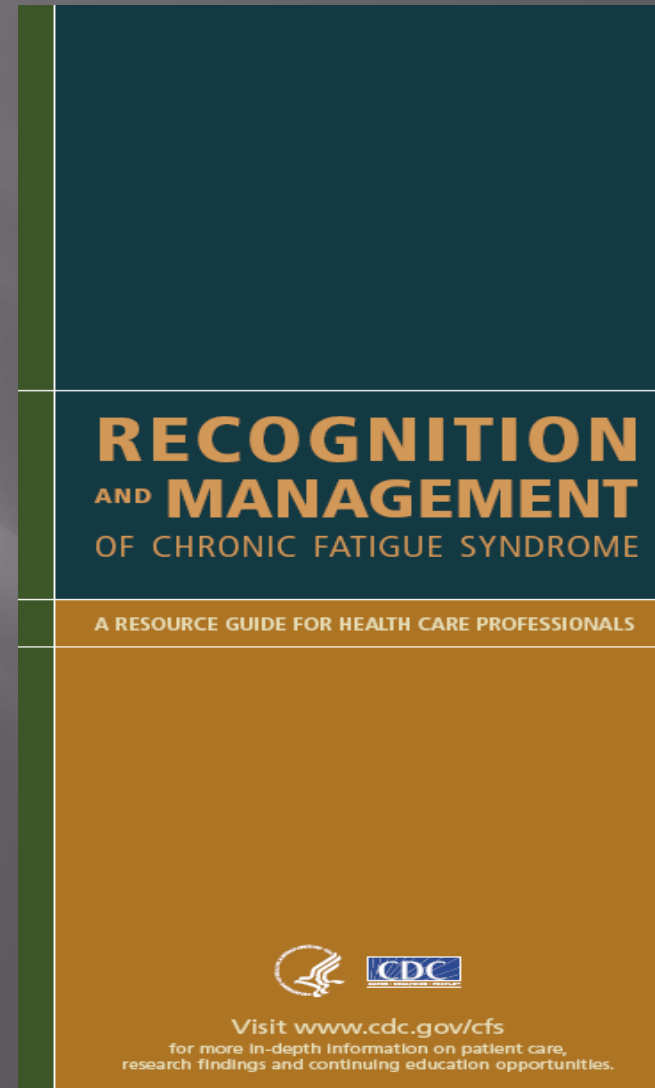
Management of Chronic Fatigue

- ▣ Often seeing individuals who are quite disabled with profound “exhausting” fatigue, having failed the management recommendations of multiple specialists.
- ▣ These are the chronically “sick of the sick” whose conditions are usually real and need to be validated.
- ▣ Need to be open minded and creatively “think out of the box,” while “doing no harm.”



Chronic Fatigue Syndrome

- ▣ Definition-
 - chronically fatiguing illness of unclear cause
 - lasting > 6 months
 - functional capacity < 50%
 - Other “causes of fatigue have been ruled out”
- ▣ Diagnosis of exclusion. There are no “markers” to define this condition.



Chronic Fatigue Syndrome

2003

HYPOTHESIS PAPER

Pathogenesis of Chronic Fatigue Syndrome, a Multisystem Hypothesis

Samuel Shor, MD, FACP

ABSTRACT. Fatigue is a very common complaint with a number of meanings. If the fatigue lasts for more than 6 months, it fulfills the definition of "chronic." The Center for Disease Control (CDC) has established specific criteria for the diagnosis of CFS. This is characterized by a persistent or relapsing debilitating fatigue for at least 6 months in the absence of a medical diagnosis that would otherwise explain the clinical presentation. CFS represents a heterogeneous group of patients that manifest symptom complexes with varying degrees of fatigue, limited exertional reserve and cognitive dysfunction. This treatise explores the pathogenesis of CFS as it relates to a complex multidimensional systemic process and offers a hypothesis for the disease processes. In particular, an up-regulated immune system, affecting mitochondrial dysfunction is described. These pathophysiologic mechanisms impact and in turn are

Samuel Shor is Associate Clinical Professor, GW University Health Care Sciences, Reston, VA.

Address correspondence to: Samuel Shor, MD, FACP, Internal Medicine of Northern Virginia, Associate Clinical Professor, GW University Health Care Sciences, 1760 Reston Parkway #310, Reston, VA 20190 (E-mail: SShor@IntmedNoVa.com).

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10.1300/J092v11n03_05

51

Chronic Fatigue Syndrome

2003

CFS

“Multisystem” Paradigm:

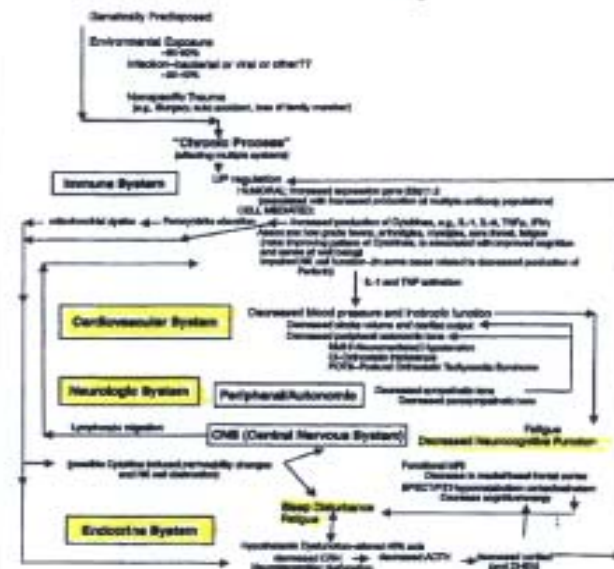
- Immune system-“up” regulated
- Cardiovascular-BP and HR
- Nervous system-sleep, cognitive
- Endocrine/Hormones-adrenal

60

JOURNAL OF CHRONIC FATIGUE SYNDROME

FIGURE 1. CFS (Chronic Fatigue Syndrome)

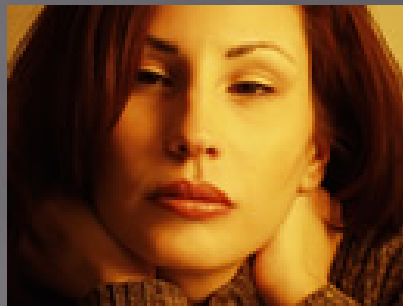
State of the Art Paradigm



sensitivity to ACTH, but a reduced maximal response. Interpretation of these findings was most consistent with "a mild central adrenal insufficiency secondary to either a deficiency of CRH or some other central stimulus to the pituitary-adrenal axis" (70). Reevaluating the CRH activation of this axis in CFS patients free from concurrent psychiatric illness, Scott et al. reported similar HPA axis dysfunction (20). A sample of 14 patients with CDC defined CFS were compared with 14 healthy volunteers. ACTH and cortisol responses were measured following the

Chronic Fatigue Syndrome

- ▣ Associated symptoms:
 - Fatigue-lack of energy reserves and “post exertional malaise”
 - Sleep disorders-nonrefreshing, fractured
 - Fibromyalgia and pain-muscle and joint
 - Cognitive “fog”
 - Hormone problems
 - ▣ adrenal dysfunction-“adrenal fatigue” low cortisol, often low DHEA, testosterone, etc
 - Blood pressure -particularly upon standing with drops in blood pressure: “dysautonomias”



Chronic Lyme Disease-ILADS

▣ ILADS

- “For the purposes of the ILADS guidelines, ‘chronic Lyme disease’ is inclusive of persistent symptomatology including fatigue, cognitive dysfunction, headaches, sleep disturbance and other neurologic features....”

Chronic Fatigue syndrome

Chronic Lyme

- ▣ Associated symptoms:
 - Fatigue-lack of energy reserves and “post exertional malaise”
 - Sleep disorders-nonrefreshing, fractured
 - Fibromyalgia and pain
 - Cognitive “fog”
 - Hormone problems
 - ▣ adrenal dysfunction-
“adrenal fatigue” low cortisol, often low DHEA, testosterone, etc
 - Blood pressure - particularly upon standing with drops in blood pressure: “dysautonomias”

Chronic Fatigue Syndrome- Lyme Disease

What is the relationship?

- ▣ Why hasn't this relationship been previously widely recognized?
- ▣ Could it be cause and effect?
- ▣ Could this be related to difficulty in diagnosing Lyme disease?

Chronic Lyme Disease

Why so much difficulty with Diagnosis? and treatment?

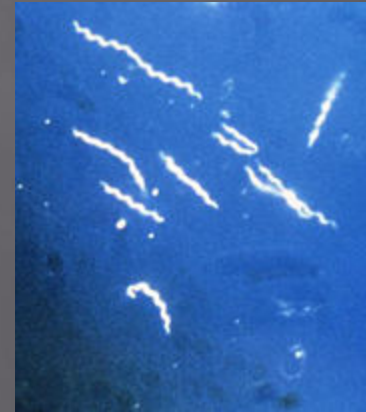
- ▣ Most diagnostic tools evaluate the immune response
- ▣ *Bburgdorferi* has evolved multiple mechanisms to elude the immune system
 - Change in outer protein coat ¹
 - Relatively immune inert “cyst” form ^{2,3}
 - Immune dysfunction-eg. CD57 ⁴
 - Production of chemicals to disable antibodies ⁵

1. Schwann TG, Piesman J, Golde WT, Dolan MC, Ros PA Induction of an outer surface protein on *Bburgdorferi* during tick feeding. *Proc Natl Acad Sci USA* 1995; 92: 2909-2913
2. Brorson O, Brorson SH Transformation of cystic forms of *Borrelia burgdorferi* to normal mobile spirochetes. *Infection* 1997; 25: 240-246
3. Gruntar I et al; Conversion of *Borrelia garinii* cystic forms to motile spirochetes in vivo. *APMIS* 2001; 109(5); 383-388
4. Stricker RB, Winger EE Decreased CD57 Lymphocyte subset in patients with chronic Lyme disease *Immunology Letters* 76 2001 43-48
5. Schutzer SE, Coyle PK, Belman AL et al Sequestration of antibody to *Borrelia burgdorferi* in immune complexes in sero-negative Lyme disease. *Lancet* 1990; 335(8685): 312-315

Chronic Lyme Disease

Evidence for persistent infection?

- ▣ Multiple reports in the literature of clear evidence for persistence of Lyme infection after “appropriate” treatment ¹⁻⁵



1. Bayer ME, Zhang L, Bayer MH *Borrelia burgdorferi* DNA in the urine of treated patients with chronic Lyme disease symptoms. A PCR study of 97 cases. *Infection* 24 (1996) 347-353
2. Nocton JJ, Dressler F, Rutledge BJ, Rys PN, Persing DH, Steere AC Detection of *Borrelia burgdorferi* DNA by polymerase chain reaction in synovial fluid from patients with Lyme arthritis *N Engl J Med* 330 (1994) 229-334
3. Preac-Mursic V, Weber K, Pfister HW, Gross WB, Baumann A, Prokop J Survival of *Borrelia burgdorferi* in Antibiotically Treated Patients with Lyme borreliosis *Infection* 17 (1989) 7-11
4. Battafarano DF, Combs JA, Enzenauer RJ, and Fitzpatrick JE Chronic Septic Arthritis Caused by *Borrelia burgdorferi* *Clinical Orthopaedics and Related Research* Number 297 (1993) 238-241
5. Schmidli J, Hunziker T, Moesli P, Schaad UB Cultivation of *Borrelia burgdorferi* from Joint Fluid Three Months After Treatment of Facial Palsy Due to Lyme Borreliosis *The Journal of Infectious Diseases* Vol 158 (4), Oct 1988 905-906

Chronic Fatigue Syndrome- Lyme Disease

What is the relationship?

- ▣ To test the hypothesis:
 - Lyme disease may actually be responsible for a CFS like syndrome
- ▣ Want to track the clinical response to Lyme directed management



Case Studies

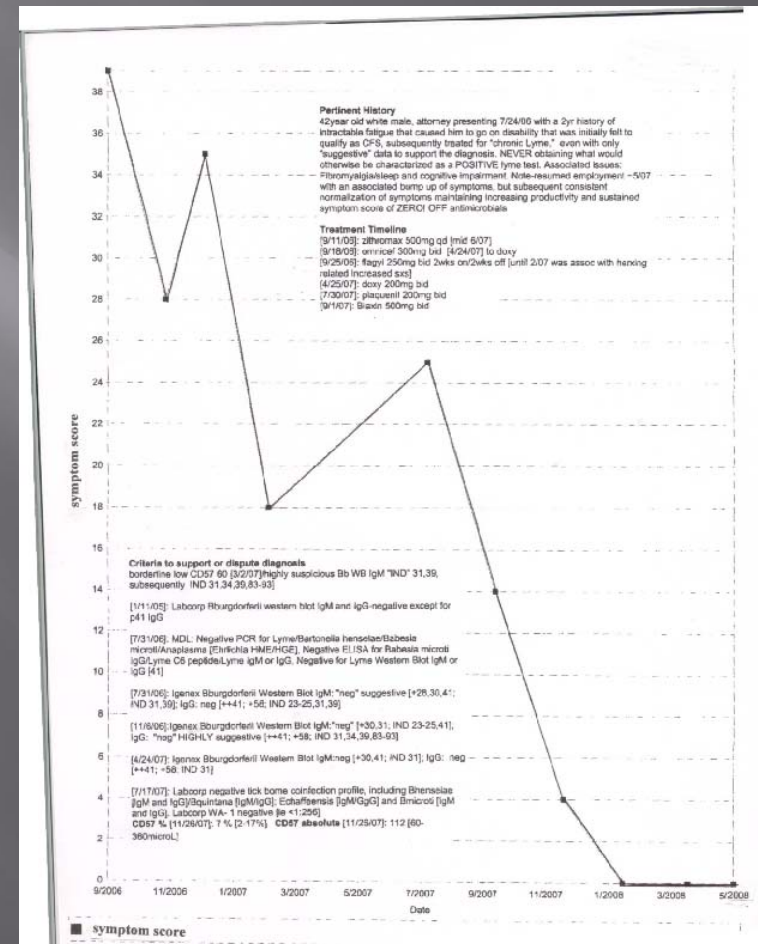
- Using symptom questionnaires completed at each office visit, in an attempt to “quantify” subjective symptomatology.

Symptom Severity Score since your last visit, or at the time of this visit if this is your first visit here: 0-none, 1 mild, 2 moderate, 3 severe				
Symptom:	0	1	2	3
unexplained fevers, sweats, chills or flushing				
unexplained weight change [loss or gain]				
fatigue, tiredness, poor stamina				
unexplained hair loss				
swollen glands				
sore throat				
testicular or pelvic pain				
unexplained menstrual irregularity				
irritable bladder or bladder dysfunction				
unexplained milk production or breast pain				
sexual dysfunction or loss of libido [sex drive]				
upset stomach or abdominal pain				
changes in bowel function-constipation and/or diarrhea				
chest pain or rib soreness				
shortness of breath or cough				
heart palpitations or skipping heart				
stiffness of the back				
muscle pain or cramps				
twitching of face or other muscles				
headache				
neck stiffness or pain				
tingling, numbness, shooting pains and/or skin sensitivities				
facial paralysis or Bell's Palsy				
joint pain or swelling				
vision problems-double, blurry, increased floaters and/or light sensitivity				
ear or hearing problems-buzzing, ringing, ear pain, sound sensitivity				
motion sickness, vertigo and/or poor balance				
lightheadedness, wooziness, unavoidable need to sit down				
tremor				
confusion and/or difficulty thinking				
difficulty with concentration and/or reading				
forgetfulness, short term memory loss, poor attention and/or problems absorbing information				
disorientation, getting lost and/or going to wrong places				
difficulty with speech, or writing or name blocking				
mood swings, irritability and/or depression				
disturbed sleep-too much, too little, frequent awakening and/or early awakening				
TOTAL [Score]				
present antibiotic regimen:				
miscellaneous comments:				

Chronic Fatigue case studies

No evidence of CDC/IDSA criteria for diagnosis of Lyme disease

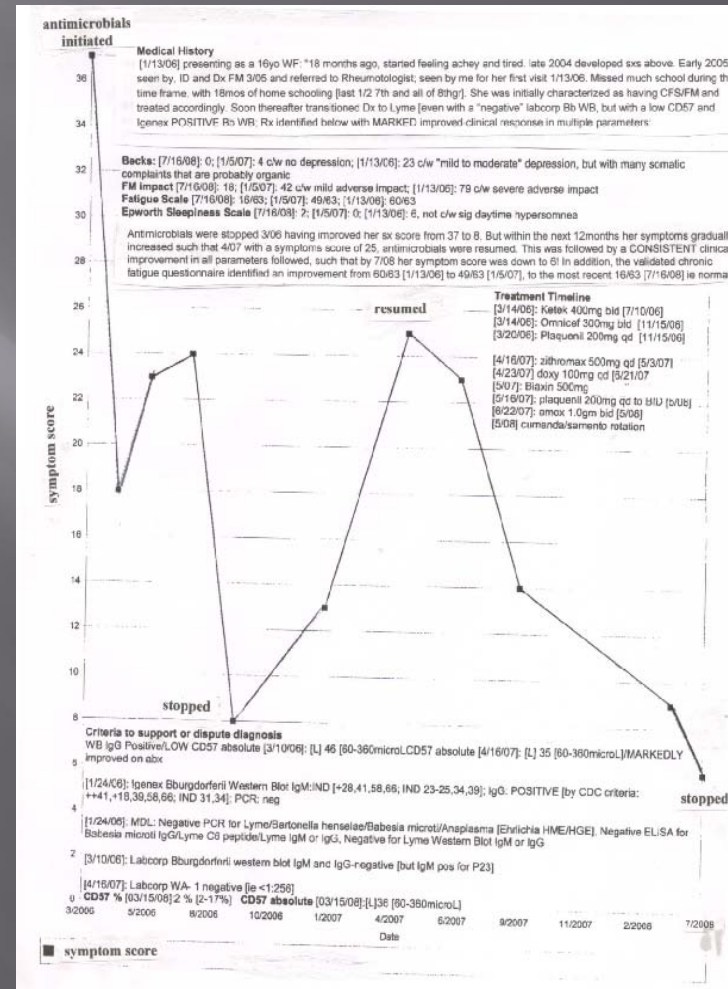
- Case study #1: 42 year old lawyer on disability for 2 years
 - Dx: CFS, subsequently “chronic Lyme”
 - NEVER meeting IDSA/CDC criteria for the diagnosis,
 - After an ILADS directed approach of antibiotics for ~15 months, he is now working full time and OFF all other “supportive” medication:



Chronic Fatigue case studies

No evidence of CDC/IDSA criteria for diagnosis of Lyme disease

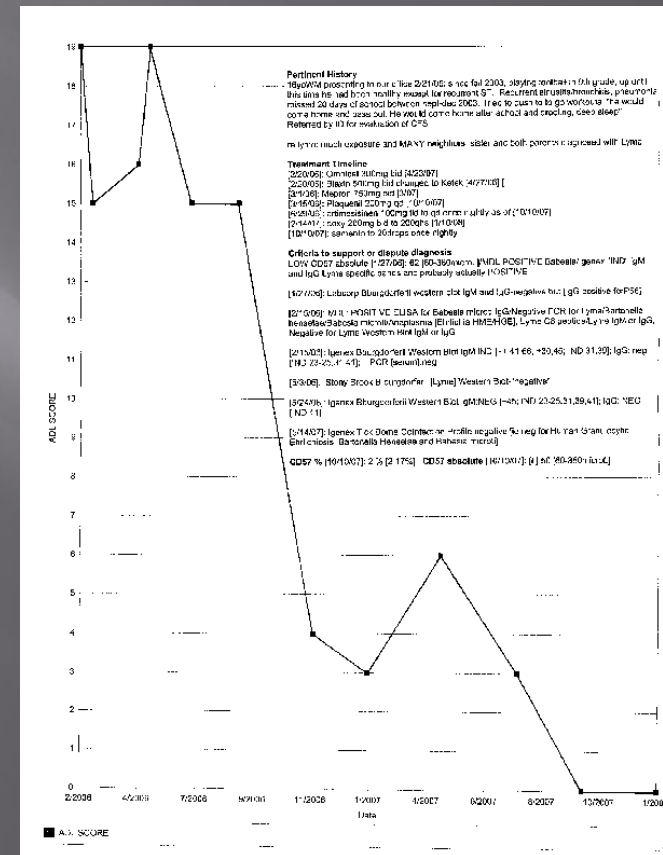
- Case study #2: 16 year female with Dx of CFS/FM, with standard IDSA/CDC preliminary studies negative for Lyme disease.
 - Subsequently characterized with Lyme disease using ILADS recommendations, treated and ultimately back to baseline.
 - Initial positive response to antimicrobials
 - Worsening when antimicrobials were stopped, without known re-exposure.
 - Normalization of symptoms when antimicrobials were resumed.



Chronic Fatigue case studies

No evidence of CDC/IDSA criteria for diagnosis of Lyme disease

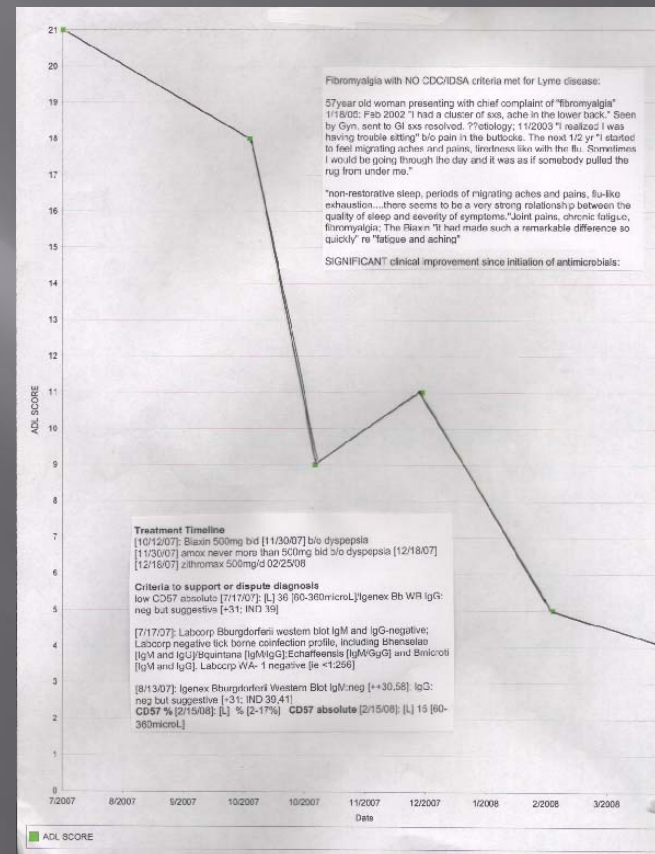
ID referred for management of CFS but actually ultimately diagnoses with Lyme. Requiring homebound schooling junior yr in HS b/o inability to keep up. After course of antimicrobials, "I am able to play basketball for 3hrs in 90deg heat"



Chronic Fatigue case studies

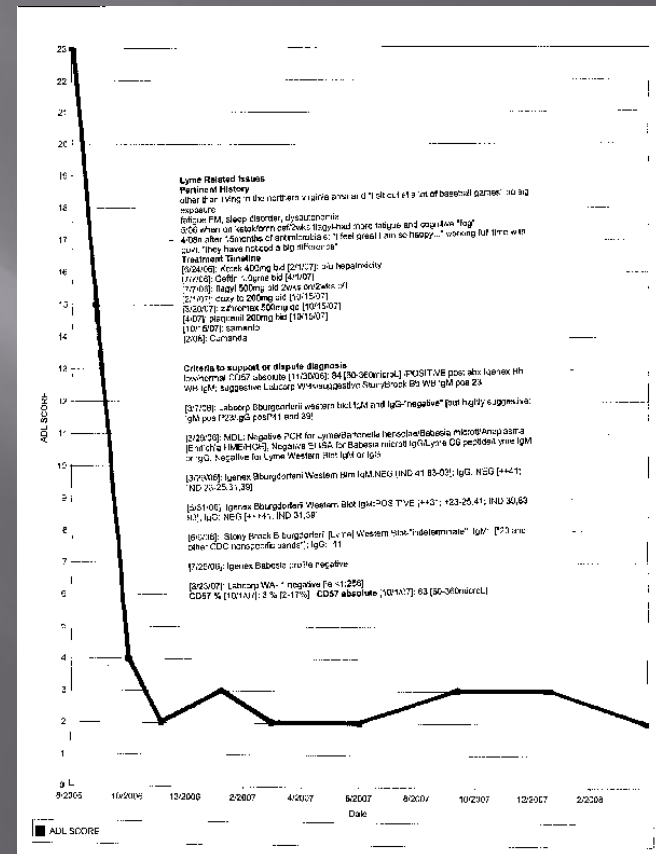
No evidence of CDC/IDSA criteria for diagnosis of Lyme disease

Fibromyalgia and chronic fatigue. Never meeting CDC/IDSA criteria. Profound improvement with antimicrobials



Chronic Fatigue case studies

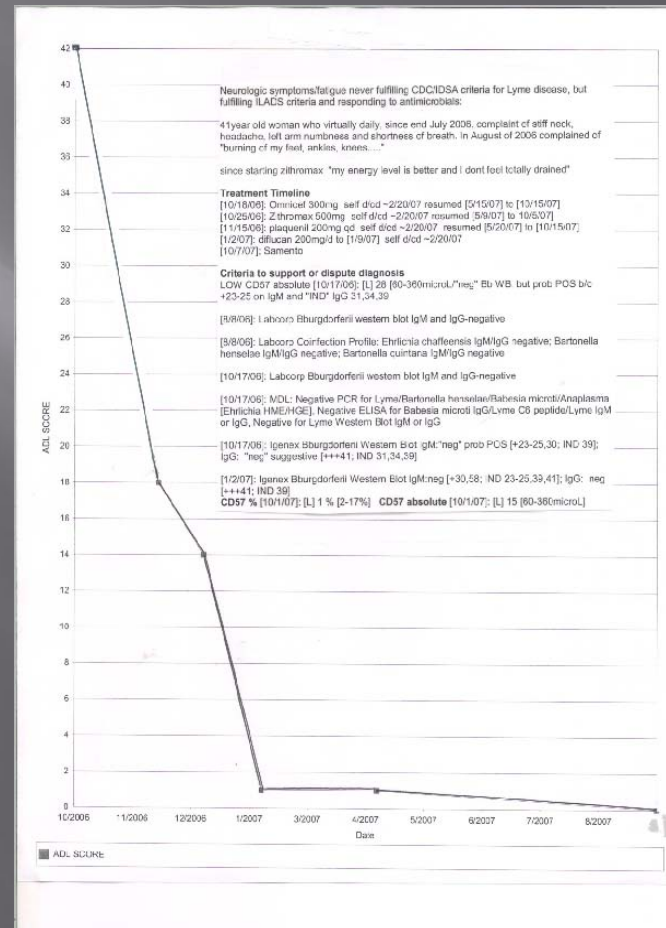
Fatigue, fibromyalgia. Negative preliminary studies, ultimately “converting” by Igenex lab to positive and profound clinical improvement on antimicrobials.



Chronic Fatigue case studies

No evidence of CDC/IDSA criteria for diagnosis of Lyme disease

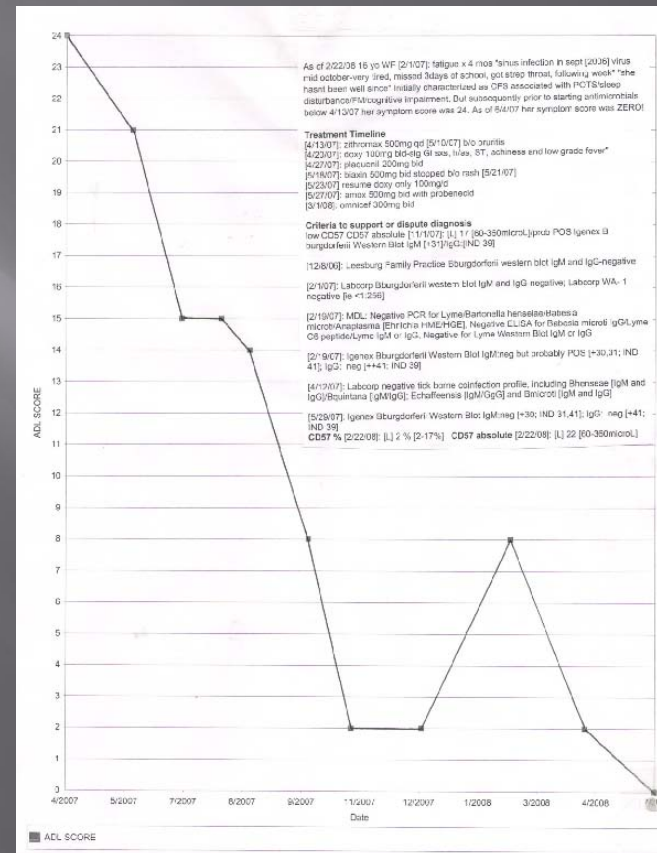
Fatigue with multiple neurologic symptoms, never meeting CDC/IDSA criteria, but meeting ILADS criteria and profound clinical improvement on antimicrobials.



Chronic Fatigue case studies

No evidence of CDC/IDSA criteria for diagnosis of Lyme disease

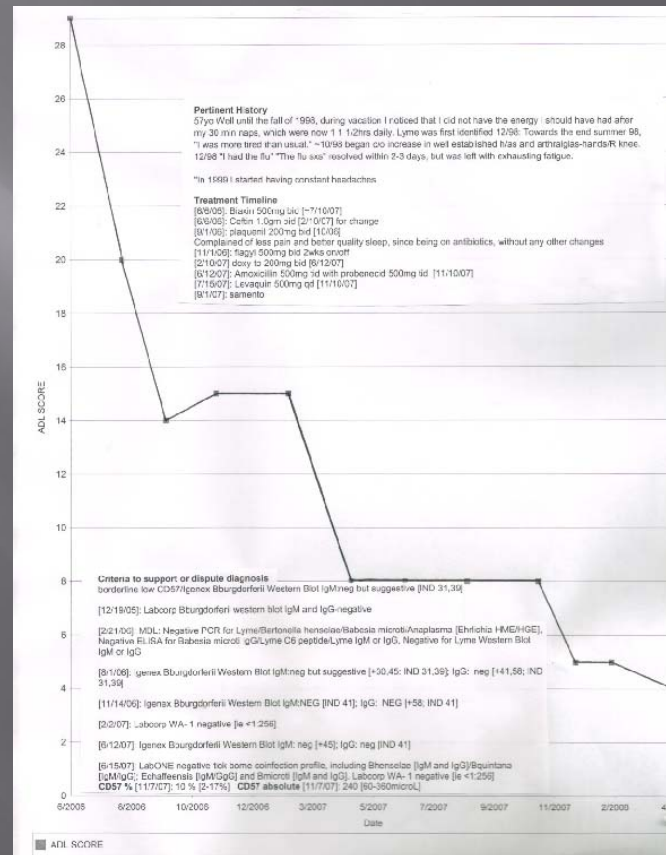
16yo initially characterized as CFS with POTS and never obtaining CDC/IDSA positivity. Initially very symptomatic and missing much school. Responding profoundly to antimicrobials with subsequent symptom score of ZERO! on very few supportive medications.



Chronic Fatigue case studies

No evidence of CDC/IDSA criteria for diagnosis of Lyme disease

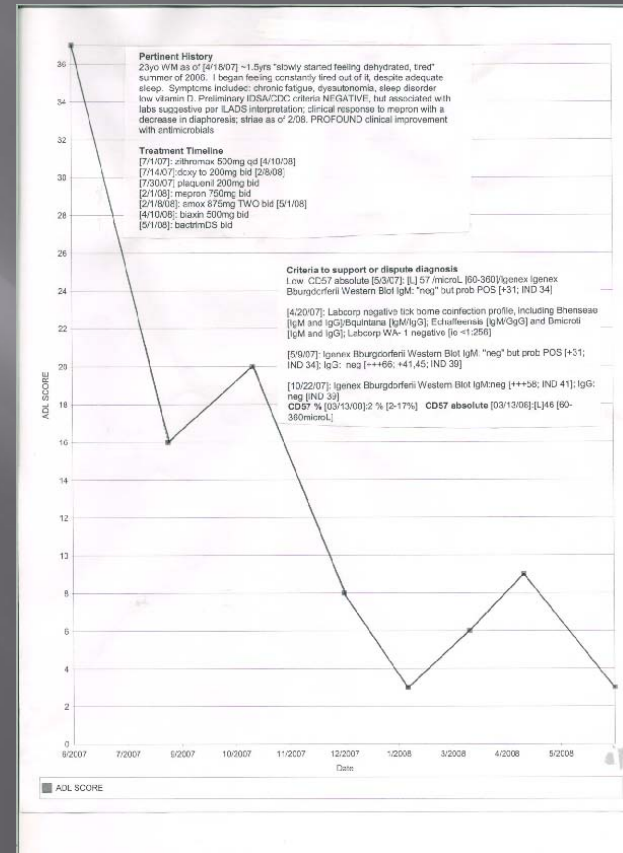
57 year old male with chronic fatigue and fibromyalgia. Marked improvement in functionality and quality of life.



Chronic Fatigue case studies

No evidence of CDC/IDSA criteria for diagnosis of Lyme disease

Clear clinical response of antibabesia treatment regarding sweats and fatigue.



Chronic Fatigue case studies

- ▣ Supporting the hypothesis that ILADS directed management has a positive clinical impact
 - Diagnosing subtle presentations outside the generally accepted “guidelines”
 - Providing clearly improved outcomes in often enigmatic cases.

Chronic Fatigue

Research-levels of credibility

- ▣ These are “anecdotal” case reports *
 - Although they are not controlled or randomized, and include additional intervention to treat other issues such as sleep, pain, etc., the ultimate outcome in most cases were individuals with far improved quality of life often on minimal supportive medications.
 - Helpful to direct insight, but not as clinically relevant as carefully performed research
- ▣ Case studies in peer review literature *
 - To allow for review and communication to the greater medical community
- ▣ Prospective, randomized controlled studies are needed**
 - To provide level 1 data-the highest level of evidence based support.

*achieved

**in process

Lyme Presenting as CFS

2006

Lyme Disease Presenting as Chronic Fatigue Syndrome

Samuel Shor, MD, FACP

ABSTRACT. *Objective:* Chronic Fatigue Syndrome (CFS) by definition represents a diagnosis of exclusion. Late stage or "Chronic Lyme" infection with or without "co-infections" is a difficult diagnosis to establish. The symptom complex of both conditions can be very similar. This case study represents an attempt to support serious consideration for a subpopulation of patients otherwise diagnosed with "CFS," as actually representing chronic Lyme disease.

Method: A case study is presented of a 33-year-old man, who for two years, was being managed as having CFS. However, after ~2 years of utilizing multiple modalities of management with limited success, the diagnosis of Lyme disease was reconsidered. Historical exposure risks to Lyme disease in this individual were high. He had prolonged exposure in the highly tick-infested mountains of North Carolina for 18 months, several years prior to becoming ill. More aggressive investigation confirmed the diagnosis of Lyme disease. Appropriate changes in management were associated with an improved level of functioning that was far in excess of what maximal management of CFS was able to achieve.

The features of CFS and chronic Lyme disease can be very similar and include the following.

Profound fatigue often associated with cognitive impairment. Other common symptoms related to both of these conditions include sleep disturbances, fibromyalgia, and dysautonomias. In pursuing clarification of this diagnosis, the author was exposed to a contrast in medical opinion regarding diagnostic tools and criteria that were perceived as creating

Samuel Shor is Associate Clinical Professor, George Washington University Health Care Sciences.

Address correspondence to: Samuel Shor, MD, FACP, 1860 Towa Center Drive #230, Reston, VA 20190 (E-mail: sshor@inmednova.com).

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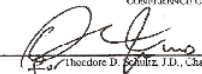
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doi:10.1300/J092v13n04_06

67

Lyme Presenting as CFS

- Proposed research
 - Shor, S A pilot study-a prospective, double blinded cross over therapeutic trial in International case defined CFS patients, who are ELISA Lyme negative, but ILADS criteria positive
- Pending NIH grant application funding

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THE FOLLOWING WERE APPROVED: INVESTIGATOR: Samuel Shor M.D. Suite 230 1860 Town Center Drive Reston, Virginia 20190		BOARD ACTION DATED: 03/06/2008 PANEL: 13 STUDY APPROVAL EXPIRES: 09/06/2008 STUDY NUM: 1006088 WIRB PRO NUM: 20072313 INVEST NUM: 157921 WIRB NUM: 1-4498171-1 CONTINUING REVIEW: Semi-Annual SITE STATUS REPORTING: Quarterly	
SPONSOR: Samuel Shor, M.D. PROTOCOL NUM: NONE! AMBI. PRO NUM: TITLE: A pilot study-a prospective, double blinded cross over therapeutic trial in International case defined CFS patients, who are ELISA Lyme negative, but ILADS criteria positive			
APPROVAL INCLUDES: Investigator Administrative Letter (02-27-2008) (TC) Symptom Inventory (Original Version 05212978.0 - As Submitted) Protocol (01-26-2008) Consent Form (SD)			
WIRB APPROVAL IS GRANTED SUBJECT TO: Exclude pregnant women. The Board directed that persons who are unable to read are not allowed to consent for themselves or others to participate in this study. The Board requires that all subjects must be able to consent for themselves to be enrolled in this study.			
<p>IF YOU HAVE ANY QUESTIONS, CONTACT WIRB AT 1-800-562-4789</p> <p>This is to certify that the information contained herein is true and correct as reflected in the records of the Western Institutional Review Board (WIRB). WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONIZATION (ICH) GUIDELINES.</p> <div style="display: flex; justify-content: space-between;"> <div>  Theodore D. Smith, J.D., Chairman </div> <div> 3/12/08 (Date) </div> </div> <p style="text-align: right;">Page 1 of 2</p> <p style="text-align: right; font-size: small;">Copyright © 2006 Western Institutional Review Board, Inc. All rights reserved.</p>			

Lyme Disease

Where Does This Leave us?



Exclusive, with strongly worded guidelines that are highly restrictive for management outside of these guidelines



Attempting to broaden the perspective and educate both the public and the medical communities about the controversies in an attempt to achieve reconciliation.

Lyme Disease

Where Does This Leave us?

October 2007

- ❑ Connecticut Attorney General investigating improprieties of IDSA guidelines:
- ❑ “American Academy of Neurology subpoenaed as Part of Investigation into Treatment Parameters for Lyme Disease”

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Guidelines on Trial: AAN Subpoenaed as Part of Investigation into Treatment Parameters for Lyme Disease

By Lisa Phillips

Connecticut Attorney General Richard Blumenthal is investigating treatment guidelines for serious system Lyme disease issued in October 2006 by the Infectious Diseases Society of America (IDSA). As a part of that investigation, the Attorney General recently subpoenaed documents related to the AAN's Lyme disease guidelines first published May 23 online in advance of the print edition of *Neurology* (2007;69:91-102).

Both sets of guidelines support conventionally recommended antibiotics for



Deferring recommendations regarding treatment for Lyme disease between two major infectious disease organizations — the Infectious Diseases Society of America (IDSA) and the International Lyme and Associated Diseases Society — have prompted an investigation into whether the IDSA guidelines constitute possible antitrust violations.

treatment of the infectious disease caused by the tick-borne spirochete *Borrelia burgdorferi*. The guidelines found evidence of no beneficial effect from using antibiotics for more than 30 days in patients diagnosed with post-Lyme syndrome (PLS). Symptoms include neu-

Continued on page 22



A variety of neurostimulators are available. As shown here, an implanted lead (a flexible insulated wire), powered by an implanted battery or a receiver, is placed near the spinal cord. The lead and the implanted stimulator send electronic impulses that block the pain messages to the brain.

Spinal Cord Stimulation Found Effective for Chronic Neuropathic Pain After Back Surgery

By Tom Valeo

Spinal cord stimulation (SCS) provides for better pain relief than conventional medical management for chronic neuropathic pain that follows failed back surgery, according to a controlled, randomized study of 100 patients. The paper appeared Sept. 12 online in advance of the print publication of *Pain*.

“This is the paper that the field of pain management has been waiting for,” said Ali R. Rezai, MD, professor of neurosurgery and director of the Center for Neurological Restoration at the Cleveland Clinic, who was not involved with the study. “It’s an excellent study, and long overdue. It may affect reimbursement from insurance companies for spinal cord stimulation because it is one of the more rigorous and controlled studies that allows for a more effective argument that spinal cord stimulation is beneficial.”

Spinal surgery to relieve chronic neuropathic pain fails so often that it has been

Continued on page 18

HIGHLIGHTS

Electron Level Linked to Demerol Risk 5

New Criteria Proposed for Diagnosing Neurodermatitis 33

Positing New Marker to Detect Early HIV Infection 39

Trial Weighs Aids of Disease-Modifying MS Drugs 25

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Lyme Disease

Where Does This Leave us?

May 2008

“The IDSA’s guideline panel improperly ignored or minimized consideration of alternative medical opinion and evidence regarding chronic Lyme disease, potentially raising serious questions about whether the recommendations reflected all relevant science.”

**News from**
Attorney General
Richard Blumenthal

Office of the Attorney General
55 Elm Street
Hartford, Connecticut 06108

For
Immediate
Release

THURSDAY, MAY 1, 2008

ATTORNEY GENERAL'S INVESTIGATION REVEALS FLAWED LYME DISEASE GUIDELINE PROCESS, IDSA AGREES TO REASSESS GUIDELINES, INSTALL INDEPENDENT ARBITER

Attorney General Richard Blumenthal today announced that his antitrust investigation has uncovered serious flaws in the Infectious Diseases Society of America's (IDSA) process for writing its 2006 Lyme disease guidelines and the IDSA has agreed to reassess them with the assistance of an outside arbiter.

The IDSA guidelines have sweeping and significant impacts on Lyme disease medical care. They are commonly applied by insurance companies in restricting coverage for long-term antibiotic treatment or other medical care and also strongly influence physician treatment decisions.

Insurance companies have denied coverage for long-term antibiotic treatment relying on these guidelines as justification. The guidelines are also widely cited for conclusions that chronic Lyme disease is nonexistent.

"This agreement vindicates my investigation -- finding undisclosed financial interests and forcing a reassessment of IDSA guidelines," Blumenthal said. "My office uncovered undisclosed financial interests held by several of the most powerful IDSA panelists. The IDSA's guideline panel improperly ignored or minimized consideration of alternative medical opinion and evidence regarding chronic Lyme disease, potentially raising serious questions about whether the recommendations reflected all relevant science."

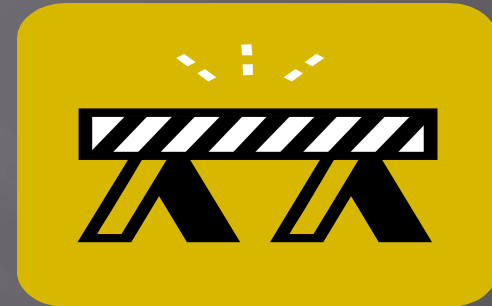
"The IDSA's Lyme guideline process lacked important procedural safeguards requiring complete reevaluation of the 2006 Lyme disease guidelines -- in effect a comprehensive reassessment through a new panel. The new panel will accept and analyze all evidence, including divergent opinion. An independent neutral ombudsman -- expert in medical ethics and conflicts of interest, selected by both the IDSA and my office -- will assess the new panel for conflicts of interests and ensure its integrity."

Blumenthal's findings include the following:

Contact: Christopher Hoffman or Tara Stapleton 860-808-5324

Chronic Fatigue/Lyme-Reality check

▣ Potential barriers:



- “sensitized” clinicians regarding “Lyme” disease
- As a result of this “sensitization,” many clinicians emphasize strict adherence to CDC guidelines [even though they are probably flawed]. But they often outright reject alternative interpretations, OR alternative laboratory evaluation.

Lyme Disease

Where Does This Leave us?

- ▣ Reassessing the present guidelines
 - Recognizing that there is much denial by the part of IDSA and subsequently the majority of the medical and lay communities [including insurance companies]
 - Requiring open minded, balanced research and assessment of that research.
- ▣ Increased awareness and education of both the medical and lay communities
 - This is an important step in that process



LYME DISEASE AND “CHRONIC LYME”

What is the controversy all about?

August 5, 2008

Samuel Shor, MD, FACP
Associate Clinical Professor
George Washington University
Health Care Sciences
Internal Medicine of Northern Virginia
1860 Town Center Drive #230
Reston, Virginia 20190
703 709-1119

